DEC 1 6 2011 K112623

510(k) Summary

Summary Prepared Date: 11/21/2011

Submission Sponsor:

Beyes Dental Canada Inc.
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Mr. Ted Thompson
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Submission Correspondent:

Mr. Anthony Hopkins
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Trade/Device Name:
Airlight Dental Handpiece Series, models M600 and M800

Common or Usual Name: handpiece, air-powered, dental
Device Class: I
Classification Name: handpiece, air-powered, dental
Regulation Number: 21 CFR 872.4200
Product Code: EFB
Review Panel: Dental

Predicate Device:

- K052822, THUNGER TIGER CORP.
  TIGER 100, TIGER 101, TIGER 200, TIGER 201, TIGER 202
- K062812, THUNGER TIGER CORP.
  TIGER 300T, TIGER 300K, TIGER 300W, TIGER 300B, TIGER 300N
- K062740, JINDELL MEDICAL INSTRUMENTS CO., LTD.
  JINDELL HIGH SPPED AIR TURBINE HANDPIECE, MODELS SW, SP, SU, ETU, MU
- K093084, ROLENCE ENT INC.
  ROLENCE DENTAL HIGH SPEED HANDPIECE, RHP
- K063110, SHANGHAI DENTAL INSTRUMENT FACTORY
  CST61 HIGH SPEED TURBINE HANDPIECE
- K021250, MK-DENT PUSH BUTTON HIGHSPEED HANDPIECE, 4 HOLES, MODELS HS 2012 (STANDARD HEAD) & HS 2014 (SMALL HEAD)
- K101551, DELMA MEDICAL INSTRUMENT (GUANGZHOU) CO., LTD.
  PACEMAKER HIGH-SPEED HANDPIECE, MODELS PM-MQ AND PM-M

Device Description:

The Airlight Dental Handpiece is a high speed dental handpiece with a lightly textured finish for enhanced grip. It is a hand-held, channeled instrument that is powered by compressed air that is delivered through a hose to an air channel in the handpiece. This impels the turbine in the head of the handpiece to revolve. Other internal channels deliver air and water to the head for cleaning and cooling. Any common dental bur is held in place in the handpiece head by a push-button.

There are three major parts which are made metal: a standard turbine, the threaded connector at the back end which attaches to the standard air/water hose in the dental unit, and the internal tubes that carry the chip air and water. These three parts are substantially equivalent to those in the predicate device.

Similar to the predicate device, the Airlight Dental Handpiece must be cleaned and lubricated with a quality commercial dental handpiece cleaner/lubricant. It is

supplied non-sterile, but must be sterilized before use, as with the predicate device. It will be packaged as a single unit or in multiples.

Intended Use:

Airlight Dental Handpiece, models M600 and M800 are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

Comparison to Predicate Devices:

The Airlight Dental Handpiece is essentially the same as or similar to the predicate device in terms of the intended use, design and construction, performance characteristics. The materials used are well-known biocompatible, so no new issues of biocompatibility are raised with regard to this device.

Discussion of Non-Clinical Tests Performed:

The performance of Airlight Dental Handpiece following ISO 7785-1:1997 and ISO 9168:1991 were conducted.

Discussion of Clinical Tests Performed:

None

Conclusion:

The proposed device has the same intended uses and indications, similar technological characteristics, and principles of operation as its predicate device. Thus, the Airlight Dental Handpiece, models M600 and M800 are substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Beyes Dental Canada Incorporated
C/O Mr. Anthony Hopkins
Regulatory Affairs Specialist
MEDevice Services, LLC
3500 South Dupont Highway
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DEC 16 2011

Re: K112623
Trade/Device Name: Airlight Dental Handpiece Series, Models M600 and M800
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: November 21, 2011
Received: December 12, 2011

Dear Mr. Hopkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112623

Device Name: Airlight Dental Handpiece Series, models M600 and M800

Indications for Use:

Airlight Dental Handpiece Series, models M600 and M800 are intended for removing carious material, reducing hard tooth structure, cavity preparation, finishing tooth preparations and restorations and polishing teeth.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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